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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,593	12/05/2001	Katherine S. Bowdish	1087-2	3532

7590 05/13/2003

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EXAMINER
HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
1642	10

DATE MAILED: 05/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,593	BOWDISH ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-95 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-95 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23, 36, 44-45, 83, 85-92, drawn to an immunoglobulin with a portion of the CDR replaced with a EPO or TPO mimetic, classified in class 530, subclass 387.3.

II. Claims 24-35, 37-39, 46-48, 65-72, 74-75, 80-82, 95, drawn to nucleic acids, vectors and host cells and method of expression, classified in class 536, subclass 23.53.

III. Claims 40-42, drawn to a method of stimulating proliferation by contacting with an antibody with a CDR replaced with a TPO mimetic, classified in class 424, subclass 130.1.

IV. Claim 43, drawn to a method of increasing the production of red blood cells with an antibody with CDR replaced with EPO mimetic, classified in class 424, subclass 130.1.

V. Claim 49-64, 73, 78-79, 84, 93, drawn to an immunoglobulin with a CDR fused to an EPO or TPO mimetic, classified in class 530, subclass 387.1.

VI. Claim 76, drawn to a method of stimulating proliferation with an antibody having a CDR fused to TPO mimetic, classified in class 424, subclass 130.

VII. Claim 77, drawn to a method of increasing the production of red blood cells with an antibody with CDR fused to EPO mimetic, classified in class 424, subclass 130.1.

VIII. Claim 94, drawn to a method of determining whether a substance has cMpl receptor activity, classified in class 435 subclass 7.1, for example.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II, and V represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The polynucleic acid of Group II, and the antibody of Groups I and V are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, while the antibody is raised by immunization or recombinant procedures. Furthermore, the polynucleotide can be used for hybridization screening, and the antibody can be used to immunopurify the antigen, for example. In addition Groups I and V are distinct because Group I requires replacement of a CDR and Group V requires fusion to a CDR which are structurally different. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I, II, and V are patentably distinct.

The methods of Inventions III-IV and VI-VIII differ in the method objectives, method steps and parameters and in the reagents used. Invention IIII recites a method of stimulating proliferation by contacting with an antibody with a CDR replaced with a

TPO mimetic; Invention IV recites a method of increasing the production of red blood cells with an antibody with CDR replaced with EPO mimetic; Invention VI recites a method of stimulating proliferation with an antibody having a CDR fused to TPO mimetic; Invention VII recite a method of increasing the production of red blood cells with an antibody with CDR fused to EPO mimetic a method of diagnosis by screening for DNA mutations and Invention VIII recites a method of determining whether a substance has cMpl receptor activity. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions III-IV and VI-VIII differ in the method objectives, method steps and parameters and in the reagents used and are patentably distinct.

Inventions I and III-IV are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the product of Group I can be used in either of the materially different methods of Groups III or IV.

Inventions V and VI-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case In this case the product of Group V can be used in either of the materially different methods of Groups VII or VIII.

3. This application contains claims directed to the following patentably distinct species of the claimed invention.

If Groups I or II are elected then a species election is required of the following species:

Species A-C are SEQ ID NO:1-3

Species D-P are SEQ ID NO:25, 27, 29, 31, 33, 35, 37, 39, 41, 43, 45, 47, and 49, respectively.

The species are distinct because art on one would not be art on the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D., whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday

from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,
Larry R. Helms Ph.D.
703-306-5879